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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,194	06/02/2006	Johannes Bartholomaus	512100-2057	3326

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EXAMINER	
YU, GINA C	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
09/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,194	BARTHOLOMAUS, JOHANNES	
	Examiner	Art Unit	
	GINA C. YU	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *June 2, 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 14, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 requires the amount of glycerol based on the crosslinked hydrophilic polymers is equal to 20 % by weight. Claim 2, which depends on claim 1, broadens the limitation of the base claim by increasing the weight amount of glycerol to 20-60 % by weight.

Regarding claims 14 and 15, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). In this case, it is not clear whether the non-preferred species "animal" and "transdermal" in claims 14 and 15, respectively, should be considered as claim limitations.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4, 6, 7, 9, 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Becher (US 6153222) in view of Zerbe et al. (US 6177096 B1).

Becher teaches a dosage form in film of oral application, comprising a mixture of active ingredient, film former, and softeners. See abstract. The reference teaches using crosslinked carboxyvinyl copolymers and/or crosslinked polyvinyl pyrrolidone as film formers. See col. 2, lines 9-12. The reference teaches polyethylene glycol or glycerol as the softener. See Further substances. The film is supplied with release paper attached thereon, meeting the instant claims 9 and 13.

Becher fails to teach the amount of glycerol as based on the total amount of crosslinked hydrophilic polymers.

Although Becher teaches the active ingredients suitable for the prior art includes dentifrice agents, the reference does not teach the active pharmaceutical ingredients of instant claim 7. See Further substances.

Zerbe teaches a film containing therapeutic agents and/or breath freshening agent for use in the oral cavity. See instant claims 5 and 6. The film comprises water-soluble polymers selected from water-soluble cellulose derivatives and polyacrylates, among others. The reference teaches the film also contains one or more plasticizers. Example 1 teaches a dosage form in film form obtained from a composition comprising 6 g of glycerol and 30 g of hydroxypropylmethyl cellulose (20% of glycerol based on the total amount of the

hydrophilic polymer). See instant claim 3. The suitable pharmaceutical actives for the oral dosage forms include psychoactive drugs, antihistamines, hormones, antibiotics, and chemotherapeutics. See col. 3, lines 16 – 33.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the teachings of Becher by employing glycerol as a softener or plasticizer for the film within the weight amount as taught by Zerbe because both references are directed to dosage forms in film forms that utilize glycerol as a plasticizer and Zerbe discloses the specific weight amount of glycerol used per the weight amount of film-forming polymers used in such formulations.

Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Becher and Zerbe as applied to claims 1, 2, 6, 7, 9, 13-15 as indicated above, and further in view of Mulye (US 6946146 B2).

The references fail to teach the specific type of polymers.

Mulye teaches a polymeric film coating composition for coating a solid dosage form of a medicament, where the coating composition controls the release of the medicament. See abstract. The reference teaches the crosslinked polymethacrylate and polyacrylate polymers derivatized with hydroxyalkyl and/or ionizable acid or basic functional groups; crosslinked hydroxypropylcellulose are swellable polymer materials. See col. 11, lines 14 – 32. The reference teaches that crosslinked polymers swell in water but will not dissolve, whereas uncrosslinked polymers may dissolve subsequent to swelling. See Id. The reference also teaches crosslinked polyvinyl pyrrolidone or crosslinked polyvinyl

alcohol may be used, suggesting functional equivalency of the polymers of Becher and the present claims.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the teachings of the combined references by substituting the crosslinked polymers of Becher with crosslinked hydroxypropylmethylcellulose or crosslinked polyacrylic acid, as motivated by Mulye, because the reference suggests these crosslinked polymers are art-recognized functional equivalents which swell in water without dissolution. The skilled artisan would have had a reasonable expectation of successfully producing a dosage form in film form which swell in water but does not dissolve, by combining the teachings of the references.

Claim 1, 2, 6-9, 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Becher in view of Lydzinski et al. (US 2003/0099692).

Becher is relied upon as discussed above.

Becher fails to teach the amount of glycerol as based on the total amount of crosslinked hydrophilic polymers.

Although Becher teaches the active ingredients suitable for the prior art includes dentifrice agents, the reference does not teach the active pharmaceutical ingredients of instant claim 7. See Further substances.

Lydzinski teaches a dosage form in film form for delivering a variety of agents to a substrate, wherein the active agents may be pharmaceuticals such as dentifrice, antiseptics or agricultural agent such as fertilizers. See [0024]; Instant claims 6-8. The reference teaches plasticizers such as polyols,

particularly glycerine, is used in "any desired amount" to increase the apparent flexibility o the film, although the prior art mentions using the plasticizer up to about 15 percent by weight of starch component which forms the bases for the prior art film form. See [0026]. The reference teaches using chemically modified starches well known in the art, including crosslinked starch. See [0013].

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the teachings of Becher by applying the prior art film invention to a variety of arts, and formulate a delivery system in film form for a variety of active agents as motivated by Lydzinski.

Although Lydzinski teaches using plasticizers up to about 15 % by weight, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Since Lydzinski teaches plasticizers are used in any desired amount, and the purpose of using plasticizer is already known, discovering an optimal weight amount of the plasticizer to obtain desired flexibility would merely require routine experimentations.

Claims 1, 2, 4, 6-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carli et al. (US 5582836) in view of Lydzinski.

Carli discloses a therapeutic composition in film form for transdermal administration of at least one medicament to human, comprising at least one active-ingredient containing layer comprising crosslinked hydrophilic polymers such as crosslinked polyvinyl-pyrrolidone, See col. 2, line 6 - col. 3, line 22. The reference teaches the transdermal film may be coated with an adhesive film and/or removable protecting sheet. See col. 4, lines 6 – 9; instant claims 9 and 10. The medicaments suitable for the invention include analgesics, anesthetics, antihypertensives, antidepressants, hormones, psychoactive drugs, etc. See col. 4, lines 10-33; instant claims 7 and 8. Since the dosage form delivers the active ingredient from the film layer to the substrate, it is obvious that the composition has concentration gradient. See instant claim 11.

Carli fails to teach plasticizers.

Lydzinski teaches a dosage form in film form for delivering a variety of agents to a substrate, wherein the active agents may be pharmaceuticals such as dentifrice, antiseptics or agricultural agent such as fertilizers. See [0024]; Instant claims 6-8. Also disclosed in topical dosage forms for delivering analgesics and cosmetic agents such as skin bleaching agent, anti-wrinkle agent, and antioxidants, etc. See examples 12-18. The reference teaches plasticizers such as polyols, particularly glycerine, is used in "any desired amount" to increase the apparent flexibility of the film, although the prior art mentions using the plasticizer up to about 15 percent by weight of starch component which forms the bases for the prior art film form. See [0026]. The reference teaches using

chemically modified starches well known in the art, including crosslinked starch. See [0013].

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the teachings of Carli by incorporating plasticizers such as glycerin as motivated by Lydzinski because 1) both arts are directed to dosage forms in film forms which transdermally deliver pharmaceutical agents to skin and 2) Lydzinski teaches employing plasticizers such as glycerine to increase the apparent flexibility of the film. By combining the teachings of the references, the skilled artisan would have had a reasonable expectation of successfully producing a transdermal film dosage form with improved flexibility.

Although Lydzinski teaches using plasticizers up to about 15 % by weight, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Since Lydzinski teaches plasticizers are used in any desired amount, and the purpose of using plasticizer is already known, discovering an optimal weight amount of the plasticizer to obtain desired flexibility would merely require routine experimentations.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINA C. YU whose telephone number is (571)272-8605. The examiner can normally be reached on Monday through Thursday, from 8:00AM until 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gina C. Yu/
Primary Examiner, Art Unit 1611